UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

PHHC, LLC.) CASE NO. 1:18CV1824
Plaintiff,	JUDGE CHRISTOPHER A. BOYKO
VS.)
ALEX M. AZAR, II., et al.,	OPINION AND ORDER
Defendant.)

CHRISTOPHER A. BOYKO, J:

This matter is before the Court on Plaintiff PHHC, LLC.'s Emergency Motion for Temporary Restraining Order (ECF # 4) and Defendant Alex M Azar's Motion to Dismiss. (ECF # 19). For the following reasons, the Court denies Plaintiff's Motion and grants Defendants' Motion to Dismiss.

On August 9, 2018, Plaintiff PHHC, LLC. filed its Verified Complaint with this Court alleging procedural and substantive due process rights violations, declaratory relief and ultra vires claims against Defendant Alex M. Azar as Secretary of the United States Department of Health and Human Services ("HHS"), Seema Verma, Administrator for the Centers for Medicare and Medicaid Services ("CMS") and Palmetto GBA, LLC. That same day, PHHC filed its Emergency Motion for Temporary Restraining Order against Defendants seeking to

restrain them from attempting to recoup amounts Defendants allege Plaintiff overbilled Medicare.

According to its Verified Complaint, Plaintiff is a Medicare-certified home health agency providing skilled nursing and home health care to approximately 170 patients in the Northeast Ohio area. Plaintiff seeks to preclude Defendants from engaging in recoupment efforts based on preliminary findings that have not yet been vetted by an independent Administrative Law Judge ("ALJ"). According to Plaintiff, ALJ's lack the authority to issue injunctive relief until they issue a final determination and there is no formal administrative mechanism to request deferral of recoupment and if recoupment proceeds, Plaintiff will be bankrupted. ALJ hearings presently have a significant backlog resulting in delays of 3-5 years.

Under the present system, healthcare providers like Plaintiff provide services to Medicare beneficiaries and submit claims for payment to Defendant HHS. These claims are then processed by Defendant CMS and its contractors. CMS conducts post-payment reviews through its contractors. In 2016, an audit of 23 of Plaintiff's billing records resulted in a determination that there was an overpayment of \$59,640.99. In 2017, a review of 30 additional medical records of Plaintiff's patients resulted in a determination that Plaintiff overbilled in the amount of \$10,754,349.00 due to an extrapolation of an 87% denial rate. Furthermore, Defendant Palmetto issued a Demand Letter in 2017 to Plaintiff for \$49,413.36 for overpayments. The denials were issued due allegedly to Plaintiff's failure to meet face-to face assessment requirements, billing for unnecessary skilled nursing and physical therapy visits, invalid case plans and failure to meet certification and recertification requirements.

Plaintiff has timely requested further review but is without a remedy until a hearing with the ALJ. Plaintiff asserts it receives almost 78% of its revenue from Medicare reimbursements and recoupment will result in the closing of its business. Plaintiff seeks a TRO to prevent Defendants from proceeding with their recoupment efforts until the ALJ reviews the issue and renders a determination.

LAW AND ANALYSIS

Standard of Review

Motion to Dismiss

Fed. R. Civ. P. 12(b)(1) states in pertinent part:

Every defense, in law or fact, to a claim for relief in any pleading, whether a claim, counterclaim, cross-claim, or third-party claim, shall be asserted in the responsive pleading thereto if one is required, except that the following defenses may at the option of the pleader be made by motion: (1) lack of jurisdiction over the subject matter

When challenged on a motion to dismiss, it is plaintiff's burden to prove the existence of subject matter jurisdiction. *Rogers v. Stratton Indus.*, 798 F.2d 913, 915 (6th Cir.1986). Such challenges are brought by two different methods: (1) facial attacks and (2) factual attacks. *See, e.g., United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir.1994).

"A *facial* attack is a challenge to the sufficiency of the pleading itself. On such a motion, the court must take the material allegations of the petition as true and construed in the light most favorable to the nonmoving party." *Walters v. Leavitt*, 376 F.Supp.2d 746, 752 (E.D. Mich 2005), citing *Scheuer v. Rhodes*, 416 U.S. 232, 235-37 (1974). "A *factual* attack, on the other hand, is not a challenge to the sufficiency of the pleading's allegations, but a challenge to the factual existence of subject matter jurisdiction. On such a motion, no

presumptive truthfulness applies to the factual allegations, . . . and the court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Walters* at 752.

In deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court must accept as true all of the factual allegations contained in the complaint. *Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007). The court need not, however, accept conclusions of law as true:

Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." As the Court held in [Bell Atlantic v.] Twombly, 550 U.S. 544, 127 S. Ct. 1955 [(2007)], the pleading standard Rule 8 announces does not require "detailed factual allegations," but it demands more than an unadorned, the-Defendant-unlawfully-harmed-me accusation. *Id.* at 555. A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555. Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement." *Id.* at 557.

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 570. A claim has facial plausibility when the Plaintiff pleads factual content that allows the court to draw the reasonable inference that the Defendant is liable for the misconduct alleged. *Id.* at 556. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a Defendant has acted unlawfully. *Id.* Where a complaint pleads facts that are "merely consistent with" a Defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief." *Id.* at 557.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

According to the Sixth Circuit, the standard described in *Twombly* and *Iqbal* "obliges a pleader to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim *plausible*." *Weisbarth v. Geauga Park Dist.*, 499 F.3d 538, 541 (6th Cir. 2007) (quoting *Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2nd Cir. 2007)).

That is, "Iqbal interpreted Twombly to require more concrete allegations only in those instances in which the complaint, on its face, does not otherwise set forth a plausible claim for relief." Weisbarth, 499 F.3d at 542. A complaint should be dismissed when it fails to allege "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570.

Injunctive Relief

Injunctive relief is an extraordinary remedy and is issued cautiously and sparingly. See Weinberger v. Romero-Barcelo, 456 U.S. 305, 312-313 (1982).

Four factors must be considered when deciding whether to grant an injunction: (1) whether the movant has a strong likelihood of success on the merits; (2) whether there is a threat of irreparable harm to the movant; (3) whether others will suffer substantial harm as a result of the injunction, should it issue; and (4) whether the public interest will be served by the injunction. *See Rock & Roll Hall of Fame and Museum, Inc. v. Gentile Prods.*, 134 F. 3d 749, 753 (6th Cir. 1998); *Vittitow v. Upper Arlington*, 43 F. 3d 1100, 1109 (6th Cir. 1995) (the four factors are "not prerequisites to be met, but factors to be balanced."); *D.B. v. Lafon*, 2007 U.S. App. LEXIS 3886 (6th Cir. 2007). While no single factor will be determinative as to the appropriateness of the equitable relief sought, (*In re DeLorean Motor Co.*, 755 F. 2d 1223, 1229 (6th Cir. 1985)), "a finding that there is simply no likelihood of success on the merits is usually fatal." *Gonzales v. Nat'l Bd. of Med. Exam'rs*, 225 F. 3d 620, 625 (6th Cir. 2000).

The moving party must establish its case by clear and convincing evidence. *See Deck v. City of Toledo*, 29 F. Supp. 2d 431, 433 (N.D. Ohio 1998), *citing Garlock, Inc., v. United Seal, Inc.*, 404 F. 2d 256, 257 (6th Cir. 1968).

The Court may issue a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained. (Fed. R. Civ. P. 65c).

Plaintiff contends it is likely to prevail on the merits as the law expressly permits it an opportunity to present its defenses to an impartial ALJ but the present backlog renders that meaningless given the length of the delay, resulting in a due process violation.

Plaintiff contends it will suffer irreparable harm because taking away its revenue stream will result in its closing of its operations affecting the healthcare of its 170 plus patients and resulting in lost employment for its employees. Equities favor injunctive relief as the United States will be able to commence recoupment proceedings and interest once the process plays out should the ALJ rule in favor of recoupment. Denial of an injunction would result in a taking without adequate due process.

Plaintiff further contends the public interest supports injunction as it will preserve the status quo allowing Plaintiff to keep its employees employed and allow Plaintiff to continue serving the medical needs of its clients.

Finally, Plaintiff asks the Court to set no bond or a nominal bond because its asks simply to have the opportunity to be heard by an impartial judge which is exactly what the law allows.

Defendant argues that Plaintiff cannot demonstrate by clear and convincing evidence it has a strong likelihood of success on the merits because it lacks a clear and indisputable right to an ALJ hearing within the ninety day time frame and the Court lacks jurisdiction to hear the Complaint as Plaintiff has failed to exhaust its administrative procedures and Plaintiff has not

been denied any due process right.

The Medicare Program

According to Plaintiff's Verified Complaint, the Medicare Program was established in Title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq., to provide health insurance for individuals sixty-five years of age and older. Plaintiff is a home health service provider offering home health services to patients who are confined to their homes, under the care of a physician, in need of intermittent nursing, physical therapy and speech-language or occupational therapy services under a plan of care. To obtain Medicare reimbursement the Home Health Agency (HHA) must obtain the patient's physician's certification that the patient is homebound. In addition, there must be an initial home certification and a face-toface meeting no more than ninety days prior to the start of home health services or within thirty days after the start of home health services. The face-to-face meeting must be conducted by a physician, a nurse practitioner or clinical nurse specialist, a certified nurse midwife, or a supervised physician assistant. Defendant reimburses Medicare providers for covered claims. Defendant CMS contracts with Medicare Administrative Contractors (MAC's) to process and make payments on valid claims. Defendant Palmetto GBA, LLC is the MAC that covered Plaintiff's reimbursements.

After initial payment on the claims, there is a mechanism for post-payment review wherein third party contractors audit the MAC payment decisions to identify fraud and to recoup improper Medicare payments. These audits are performed by Zone Program Integrity Contractors (ZPIC). Audits are typically performed by reviewing a small sample of the billing (usually 50 or less samples) and then using statistical sampling, extrapolating the

overbilled number of cases to the entire billed amount. ZPICs are paid based on the recovered amount of Medicare overbilling from providers, thus, they have a financial incentive to overturn initial payment determinations. Plaintiff alleges ZPIC claim denials are overturned at the rate of 69% according to 2014 data while Senator Orrin Hatch in a 2015 Senate hearing testified that 60% of claims are overturned in the provider's favor when heard by an ALJ.

The Appeals Process

Under the Social Security Act, there is a four level appeals process for post-payment denials before judicial review is available.

The Redetermination Level is the first level of appeal wherein a provider who has a claim for payment denied may present it to the MAC for a redetermination. 42 U.S.C. § 1395ff(a)(3)(C)(ii) requires the redetermination be made within 60 days from the date the request is made. MAC's cannot proceed with recoupment once a redetermination request is filed.

The second level of appeal, called the Reconsideration Level, is heard by a Qualified Independent Contractor (QIC). The provider must appeal to the QIC within 180 days of receipt of the redetermination decision. The QIC must issue its decision within 60 days of receipt of the reconsideration request.

The third level of appeal is the ALJ level wherein a provider unsatisfied with the QIC decision must appeal within 60 days of the receipt thereof. At the ALJ level there is no restriction against recoupment, thus, after the QIC decision is issued Medicare contractors may commence recoupment efforts.

An ALJ is required to render a decision within 90 days of the filing of an appeal. If no

decision is timely rendered, the provider may seek review from the Medical Appeals Council which must render a decision in 180 days of a timely review request.

If an ALJ renders a decision a provider may appeal within 60 days to the Medicare

Appeals Council, which must render a decision in 90 days from the date of request for review.

Thereafter, a provider may request judicial review from a federal district court.

The decision of the Medicare Appeals Council is the final decision of the Secretary of Health and Human Services.

According to Plaintiff, despite the mandatory statutory decision time periods, in practice appeals take significantly longer due to the large backlog of Medicare appeals at the ALJ level. From 2009 to 2017, Medicare appeals grew from 35,831 to over 594,000 with levels projected to reach 972,591 by the end of fiscal year 2021. In 2016, the average time for adjudication of an appeal was 877 days. In 2017 it was 1051 days. Thus, the expected time waiting period for an ALJ hearing is 3 to 5 years.

Plaintiff has received unfavorable decisions at the Redetermination and Reconsideration levels of appeal. On July 13, 2018, Plaintiff timely submitted a request for an ALJ hearing and on July 24, 2018, Palmetto began recoupment proceedings.

Plaintiff moves for injunctive relief in the form of a court order preventing Palmetto from seeking further recoupment until the ALJ has rendered its decision. If the Court fails to enjoin Palmetto, Plaintiff will be forced to close its business as it cannot continue to serve its patients when over 77.6% of its revenue is derived from Medicare services.

Plaintiff's Verified Complaint alleges claims for procedural and substantive due process violations and seeks declaratory and injunctive relief as well as an ultra vires claim

for threatening recoupment without providing Plaintiff with an ALJ hearing within the statutorily mandated time period.

Defendants' Response and Motion to Dismiss

According to Defendants, Plaintiff's Motion for TRO must be denied and its claims dismissed because the Court lacks jurisdiction to hear the claims for Plaintiff's failure to exhaust its administrative remedies. Furthermore, Plaintiff's claims must be denied because it lacks a due process right to a pre-recoupment hearing.

Exhaustion as a jurisdictional prerequisite

According to Defendants, no judicial review may be held until a final decision has been rendered after a hearing. Defendants cite the Court to Section 42 U.S.C. § 405(h) which reads:

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

"Section 1395ii makes § 405(h) applicable to the Medicare Act "to the same extent as" it applies to the Social Security Act." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 9, 120 S. Ct. 1084, 1091, 146 L. Ed. 2d 1 (2000)

The plain language of the above chapter clearly limits the court's authority to review the Secretary's decision until a final decision has been made. The Sixth Circuit has held "in order to obtain judicial review under §405(g), a party must comply with '(1) a nonwaivable

requirement of presentation of any claim to the Secretary, and (2) a requirement of exhaustion of administrative review, which the Secretary may waive." Cathedral Rock of North College Hill, Inc. V. Shalala, 223 F.3d 354, 359 (6th Cir. 2000) quoting Michigan Ass'n of Homes & Services for the Aging, Inc. v. Shalala, 127 F.3d 496, 499 (6th Cir. 1997). This holding relied on the Supreme Court decision in Shalala, 529 U.S. 1, 120 S. Ct. at 1093, wherein the Supreme Court held that § 405(h) "demands the channeling of virtually all legal attacks through the agency." An exception to the exhaustion requirement was discussed in *Illinois* Council wherein the Supreme Court held that for a court to exercise jurisdiction over a claims arising out of the Medicare Act without first exhausting the administrative process, the Court must determine whether a party is "simply being required to seek review first through the agency or is being denied altogether the opportunity for judicial review." *Illinois Council* 120 S. Ct at 1096-97. Here, Plaintiff contends it would be futile to pursue its claims administratively since it will suffer irreparable harm long before the ALJ can hear its appeal. If it is forced to make over \$10,000,000.00 in recoupment payments, Plaintiff alleges it will be forced out of business in a matter of months.

Plaintiff contends its Complaint alleges its claims are not substantive claims for benefits but instead fall under the collateral exception and therefore it is not required to exhaust its claims administratively. In support of its position, Plaintiff cites to *Family Rehabilitation Inc. v. Alex Azar*, 886 F.3d 496 (5th Cir. 2018), wherein the Fifth Circuit Court of Appeals held that a district court had jurisdiction over a due process and ultra vires claim against Defendant for failing to provide a hearing prior to recoupment because the Complaint alleged a violation of Plaintiff's due process rights. There as here, the plaintiff sought to

enjoin Medicare recoupment until a hearing was held. The Fifth Circuit found such an action fell under the collateral exception found in *Eldridge*.

Likewise, in *Cathedral Rock*, the Sixth Circuit held that a plaintiff's claim for a pretermination hearing fell under plaintiff's procedural due process rights and stated a claim "entirely collateral" to a substantive challenge to the Secretary's termination decision. 223 F.3d at 364.

In its review of the above caselaw, the Court finds Plaintiff's claim falls under the collateral exception to exhaustion because Plaintiff has presented its claims to the Agency for review similar to the Plaintiff in *Eldridge*. Furthermore, as the plaintiffs in *Cathedral Rock* and *Family Rehabilitation*, Plaintiff only asks the Court to review its due process rights and does not assert claims for full payment under the Medicare Act at this time.

Having found its Complaint asserts claims entirely collateral to Plaintiff's claims for payment under the Medicare Act, the Court must next consider whether under the Due Process Clause of the United States Constitution, Plaintiff is entitled to a pre-recoupment hearing.

Due Process Rights to a Pre Recoupment Hearing

"An essential principle of due process is that a deprivation of life, liberty, or property "be preceded by notice and opportunity for hearing appropriate to the nature of the case." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542, 105 S. Ct. 1487, 1493, 84 L. Ed. 2d 494 (1985). "We have described "the root requirement" of the Due Process Clause as being "that an individual be given an opportunity for a hearing *before* he is deprived of any significant property interest." *Id.* "The essential requirements of due process...are notice and

an opportunity to respond. The opportunity to present reasons, either in person or in writing, why proposed action should not be taken is a fundamental due process requirement. *Id* at 546.

In order to establish a substantive due process claim a plaintiff must demonstrate: (1) a constitutionally protected property or liberty interest exists, and (2) the constitutionally protected interest has been deprived through arbitrary and capricious action." *EJS Properties*, *LLC*, 736 F. Supp. 2d at 1136.

"The procedural due process component, on the other hand, places constraints on the manner in which the government can deprive individuals of life, liberty, or property by prohibiting the government from depriving individuals in an unfair manner." *Shurney v. I.N.S.*, 201 F. Supp. 2d 783, 790 (N.D. Ohio 2001) citing *United States v. Salerno*, 481 U.S. 739, 746, 107 S.Ct. 2095, 95 L.Ed.2d 697 (1987); *Mathews v. Eldridge*, 424 U.S. 319, 333–35, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). In order to have a protectable property interest in a benefit, a person must have "a legitimate claim of entitlement to it." *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577, 92 S.Ct. 2701, 2709 (1972). "Entitlements are created by 'rules or understandings' from independent sources, such as statutes, regulations, and ordinances, or express or implied contracts." *Id*.

The United States Supreme Court in *Eldridge* determined the factors a court must consider when determining whether an administrative appeals scheme provides sufficient procedural safeguards to satisfy the Due Process clause of the United States Constitution.

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Eldridge, 424 U.S. at 335, 96 S.Ct. 893. Thus, in order to prevail on either a substantive or procedural due process claim, Plaintiff must establish a protectable liberty or property interest. Upon examination of these factors, the Court finds they militate against Plaintiff and in favor of Defendants.

Private Interest

Plaintiff alleges the private interest it possesses is a property interest in Medicare payments it received for providing health care to Medicare patients.

The Medicare statute confers upon the Secretary the authority to determine the amount of payment and to recoup overpayments at 42 U.S.C. §1395g(a), where it reads in pertinent part:

(a) **Determination of amount**

The Secretary shall periodically determine the amount which should be paid under this part to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate (but not less often than monthly) and prior to audit or settlement by the Government Accountability Office, from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period.

The statute does not provide Plaintiff with an unfettered right to payment, rather, the Secretary "determines the amount which should be paid"... "with necessary adjustments on account of previously made overpayments or underpayments." The statute then qualifies that payments are subject to information requested by the Secretary from the provider in order to

determine the amount of the payments "due such provider"... "being made or any prior period."

Payments to the provider and even prior payments, which are the subject of this suit, are subject to adjustments by the Secretary and are further subject to the provider supplying the information required by the Secretary in order to determine the amount of payments even for a prior payment. Because the statute contains these qualifications, the Court does not find that Plaintiff's interest in the overpayments rises to the level of a constitutionally protected property interest.

In *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40 (1999), the United States Supreme Court considered whether a state could suspend workers' compensation benefits without notice or an opportunity to be heard. While the case does not concern a federal benefits program the Court finds its holding instructive. Considering whether the plaintiffs, who were disabled employees of the State of Pennsylvania, had a protected property interest in payment for medical treatment, the Court looked to the statute to determine what rights it conferred. Because the statute made the payments conditional upon the plaintiffs' proof that the medical treatment was "reasonable and necessary," no property interest in the payments attached until plaintiffs satisfied the statutory prerequisite.

The Court holds that the same logic applies here. Plaintiff does not have a constitutionally protected property right in the overpayment until it can provide information to the Secretary that it is entitled to the full amount of the payments made.

Plaintiff acknowledges that the Sixth Circuit in *Cathedral Rock of North College Hill*, *Inc. v. Shalala* determined that providers do not have a private interest in being a Medicare

provider, however, they contend that Cathedral Rock at 365 established that they do have a property interest in the payments. The Court's reading of Cathedral Rock does not support such a conclusion. There is nothing in the decision at page 365 or elsewhere that establishes a healthcare provider's constitutional property interest in payments. Instead, Cathedral Rock does support a property interest for beneficiaries to benefits under the Medicare Act. In Cathedral Rock, a Medicare provider challenged the Health and Human Services right to terminate its status as a Medicare healthcare provider without a pre-deprivation hearing. In finding no entitlement to a pre-deprivation hearing, the Sixth Circuit determined that a healthcare provider's private interest was not "particularly strong because the Medicare provider is not the intended beneficiary of the Medicare program." *Id* at 365. The Sixth Circuit found that "termination of its agreement may have severe economic impact on the provider," however, "a provider's financial need to be subsidized for the care of Medicare patients is only incidental to the purpose and design of the [Medicare] program." *Id.* This opinion is consistent with the Sixth Circuit's findings in Green v. Cashman, 605 F.2d 945, 946 (6th Cir. 1979), wherein the Court held that Medicare and Medicaid statutes were not designed "to provide financial assistance to providers of care for their own benefit," but rather "to aid the patients and clients of such facilities." Because the Sixth Circuit found a provider's financial need to be subsidized for the care of its patients "is only incidental" to the purposes of Medicare, the Court finds Plaintiff's private interest right to payment is weak and further supports the conclusion that Plaintiff's property interest in the contested overpayments does not rise to the level of a constitutionally protected property interest. Logic would seem to dictate that a if provider's termination from the Medicare program without a pretermination hearing does not implicate a strong private interest, then neither does recoupment for a provider's overpayment. This factor weighs against Plaintiff's argument that it has a colorable claim to a pre-recoupment hearing under the Due Process clause and most certainly weighs against its right to injunctive relief, as it indicates Plaintiff is not substantially likely to succeed on the merits.

The Sixth Circuit in *Parrino*, 869 F.3d at 397–98, found a healthcare provider had no due process property or liberty interest in participating in Medicare or in reimbursements. The Sixth Circuit reasoned:

While we have not directly addressed this issue, several of our sister circuits have held that a provider does not have a property interest in continued participation in federal health care programs. See Erickson v. U.S. ex rel. Dep't of Health & Human Servs., 67 F.3d 858, 862 (9th Cir. 1995); Koerpel v. Heckler, 797 F.2d 858, 863-65 (10th Cir. 1986); Cervoni v. Sec'y of Health, Ed. & Welfare, 581 F.2d 1010, 1018-19 (1st Cir. 1978). These courts have reasoned that health care providers are not the intended beneficiaries of the federal health care programs and they therefore do not have a property interest in continued participation or reimbursement. And though the Fourth Circuit has declared that providers do have a property interest in continued participation in federal health care programs, it provided no accompanying analysis for its conclusion. Ram v. Heckler, 792 F.2d 444, 447 (4th Cir. 1986) ("Ram's expectation of continued participation in the [M]edicare program is a property interest protected by the due process clause of the fifth amendment."). We find persuasive the rationale of the First, Ninth, and Tenth Circuits in finding no property interest. This is because, although Parrino is suffering financial loss, this loss "do[es] not advance to the level of a protected property right because no clear promises have been made by the government." Koerpel, 797 F.2d at 864. (Emphasis added).

Parrino also fails to demonstrate that he has at stake a liberty interest—which he characterizes as his good name and professional reputation. We have previously stated that "a person's reputation, good name, honor, and integrity are among the liberty interests protected by the due process clause of the [F]ourteenth [A]mendment." *Quinn v. Shirey*, 293 F.3d 315, 319 (6th Cir. 2002) (citation omitted). "To establish a deprivation of a protected liberty interest in the employment context, [Parrino] must demonstrate stigmatizing governmental action which so negatively affects his ... reputation that it

effectively forecloses the opportunity to practice a chosen profession." *Joelson v. United States*, 86 F.3d 1413, 1420 (6th Cir. 1996) (citing *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 573-74, 92 S.Ct. 2701, 33 L.Ed.2d 548 (1972)). Parrino must also have "allege[d] in his ... complaint that the stigmatizing information was publicly disclosed." *Id.* (citation omitted). Although Parrino has shown that he effectively has no ability to work as a pharmacist for the duration of his exclusion, he has not argued that this "stigmatizing information" was publicly disclosed, or alleged that HHS will disclose such information in the future.

The district court was therefore correct in finding that Parrino has no substantive due process right to participate in all federal health care programs.

Id.

The same analysis applies to Plaintiff's substantive due process claim here. Plaintiff cannot show a property interest in overpayments such that the attempted recoupment of these alleged overpayments constitutes a constitutional due process violation. Plaintiff is not the intended beneficiary of the Medicare program and *Parrino* expressly found no property interest in one's provider status or in reimbursement.

Because Plaintiff cannot show a constitutionally protected right to unadjusted payments, it cannot prevail on its due process claims.

Right to a pre-recoupment hearing

Neither does the statute guarantee an ALJ hearing prior to recoupment. Under the plain language of the statute and its regulations, recoupment may commence prior to the ALJ hearing. Furthermore, the statute does not guarantee a hearing with an ALJ within the 90 day period set forth in 405(g). In *Cumberland Cty. Hosp. Sys., Inc. v. Burwell*, 816 F.3d 48, 50 (4th Cir. 2016), the Fourth Circuit determined there was no guarantee of an ALJ hearing within 90 days under the statute. In so holding, the Fourth Circuit wrote:

While we agree that the delay in the administrative process for Medicare reimbursement is incontrovertibly grotesque, the Medicare Act does not

guarantee a healthcare provider a hearing before an ALJ within 90 days, as the Hospital System claims. Rather, it provides a comprehensive administrative process—which includes deadlines and consequences for missed deadlines—that a healthcare provider must exhaust before ultimately obtaining review in a United States district court. Indeed, within that administrative process, a healthcare provider can bypass administrative reviews if such reviews are delayed, "escalating" for review by a United States district court within a relatively expeditious time.

As the Fourth Circuit described, the statutory scheme for appealing a decision on payment expressly contemplates that a decision by both the ALJ and the Departmental Appeals Board of the Department of Health and Human Services may not be rendered within the time frame required under the statute. In such cases the statute allows for escalation of a provider's claim for judicial review should the ALJ and subsequent appeal Board fail to render timely decisions. Consequently, the plain language of the statutory appeals process does not confer a procedural due process right to an ALJ hearing prior to recoupment. This is also consistent with the Supreme Court's rationale in *Eldridge* wherein the Court determined that no evidentiary hearing was required under the due process clause prior to terminating a social security recipient's benefits under the same administrative procedures before the Court in this matter. See *Eldridge*, 424 U.S. at 340.

The Court notes an important distinction here, that Plaintiff has already been paid by Defendant for medical services rendered such that the Defendant fulfilled its obligations to pay for the work performed. It is not the payment for services rendered that Defendant has denied Plaintiff, rather it is the alleged overpayment for those services Defendant seeks to recoup. In light of the above, the Court finds there is simply no property interest in

overpayments. 1

Likewise Plaintiff has not alleged a sufficient liberty interest. Plaintiff asserts no plausible claim that recoupment of overpayments negatively affects its good name or reputation. Defendant does not allege a fraud or some misdeed of Plaintiff that would impugn Plaintiff's reputation or ability to provide further healthcare services. Thus, no liberty interest is implicated. See *Joelson v. United States*, 86 F.3d 1413, 1420 (6th Cir. 1996) (citing *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 573-74, 92 S.Ct. 2701, 33 L.Ed.2d 548 (1972)). ("To establish a deprivation of a protected liberty interest in the employment context, [plaintiff] must demonstrate stigmatizing governmental action which so negatively affects his ... reputation that it effectively forecloses the opportunity to practice a chosen profession."²

Because Plaintiff lacks a property interest, it cannot show a substantial likelihood of success on the merits and it is not entitled to an injunction. Furthermore, because it lacks a property or liberty interest, its Due Process claims fail as a matter of law, as does its claim for Declaratory Judgment, which is dependent on a determination that they are entitled to an ALJ hearing in the time frame set forth in the Medicare statute.

Risk of Erroneous Result

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Plaintiff has pointed the Court to cases that have found a property interest in payment. See *Morrison v. Sebelius*, No. 2:11CV1002, 2013 WL 3288167 (S.D. Ohio June 28, 2013) and *A1 Diabetes & Med Supply v. Azar*, 2:18CV2612 (W.D. Tenn. Oct. 12, 2018) but neither of these cases rely on caselaw constituting binding precedent upon this court and do not persuade the Court that the Sixth Circuit would so find in light of the Sixth Circuit holdings in *Cathedral Rock* and *Parrino*.

Plaintiff's Opposition Brief does not argue for a liberty interest and appears to have abandoned such a claim.

The Court must next examine the extent of the "risk of an erroneous deprivation of [Plaintiff's private interest] through the procedures used, and the probable value, if any of additional or substitute procedural safeguards." *Cathedral Rock*, 223 F.3d at 364, quoting *Eldridge*, 424 U.S. at 335. 42 U.S.C. § 1395ff does not permit recoupment until a provider has had its billing subject to two levels of review. After a determination of overpayment is made and conveyed to the provider, the provider may offer a rebuttal to include any pertinent information relating to the legitimacy of the billed amount to the Medicare contractor. Then a redetermination is made after consideration of the rebuttal arguments and information. The redetermination must be made by someone other than the person who made the initial determination. § 1395(a)(3)(B)(iii). During the appeals process the provider may be represented by counsel and may present medical records and expert opinions. See 42 CFR § 405.910 and .946 respectively. After the redetermination, the MAC provides a written determination explaining the decision. The provider then may appeal to the QIC. This appeal called a reconsideration, involves the following:

A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's reconsideration must involve consideration by a panel of physicians or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

42 C.F.R. § 405.968.

It is only after the QIC issues its reconsideration that recoupment may commence.

Thus, the procedures in place prior to recoupment provide for representation, multiple levels of review by different individuals and an opportunity to provide evidence and expert testimony. The Sixth Circuit in *Cathedral Rock* relied on a case out of the Seventh Circuit *Northlake Community Hospital v. United States* 654 F.2d 1234 (7th Cir. 1981) wherein the court, in applying the risk of erroneous deprivation factor, found the procedures in place presented a low risk of an erroneous deprivation. In relying on *Northlake*, the Sixth Circuit agreed that "the provider has the opportunity to submit written material in response to survey findings so that a hearing likely is not necessary for the provider to present its position." *Cathedral Rock*, 223 F.3d at 365. This decision echoes the majority of decisions, albeit in the context of termination of participation in the Medicare field that no pre-deprivation hearing is required or mandated by due process.

Plaintiff contends that the percentage of reversals at the ALJ level are high, exceeding fifty percent. However, those figures appear to be outdated as Defendant points out, citing to the 2017 Fiscal Year statistics wherein ALJ's returned 25.9% favorable decisions for appellants either in full or in part. Statistics for 2018 thus far show only an 18.2% favorable decisions for appellants at the ALJ level. See https://www.hhs.gov/about/agencies/ omha/about/current-workload/decision-statistics/index.html. (Run date July 16, 2018.) While this may not speak definitively to the risk of an erroneous deprivation it does demonstrate that it is statistically far more likely that the Government will prevail at the appellate level. Thus, there does not appear to be a substantial risk of erroneous deprivation, from a delay in an ALJ hearing.

Interest of the Government

The last factor for the Court to consider is the Government's interest, "including the function involved and the fiscal and administrative burdens that any additional or substitute procedural requirement would entail." *Eldridge*, 424 U.S. at 335. We begin with *Eldridge* wherein the Supreme Court found this factor weighed heavily in favor of the procedures in place. The Supreme Court concluded that the administrative burden and societal costs, including the expense of providing benefits to someone ineligible before a final decision can be rendered, would not only be substantial, but would outweigh any "increased assurance that the action is just." *Id* at 348. In concluding that the Governmental interest in pre-hearing termination outweighed the individual's interest in a pre-termination hearing, the Supreme Court concluded "the cost of protecting those whom the preliminary administrative process has identified as likely to be found undeserving may in the end come out of the pockets of the deserving since resources available for any particular program of social welfare are not unlimited." *Id*.

This logic compels this Court's decision. Just as the Government has a strong interest in terminating the undeserving from the Medicare program, it has an equally strong interest in recouping overpayments. The resources of the Medicare program are limited and the Government is tasked with the obligation to see that providers are paid only for those services expressly authorized or permitted by Medicare and any such overpayments deplete the limited resources of the program for those services that are authorized. In short, "the needs of the many outweigh the needs of the few."

Thus, in light of the above factors the Court finds Plaintiff is not entitled to an injunction on recoupment until after an ALJ hearing is conducted. Its weak private interest

does not outweigh the Government's strong interest in recoupment of overpayments and the Court is convinced under applicable case law that no pre-recoupment hearing is mandated by the Due Process Clause as the process in place provides a full opportunity for Plaintiff to be heard prior to recoupment. Furthermore, Plaintiff has the means available to them under the administrative process to expedite review up to, and including, district court review. In *Eldridge*, the Supreme Court concluded by saying:

All that is necessary is the procedures be tailored, in light of the decision to be made, to the capacities and circumstances of those who are to be heard, (internal citations and quotations omitted) to insure that they are given a meaningful opportunity to present their case. In assessing what process is due in this case, substantial weight must be given to the good-faith judgments of the individuals charged by Congress with the administration of social welfare programs that the procedures they have provided assure fair consideration of the entitlement claims of individuals."

Eldridge, 424 U.S. at 349.

Because Plaintiff cannot show a deprivation of a due process right, the Court finds Plaintiff has failed to meet its burden by clear and convincing evidence to show it has a substantial likelihood of success on the merits as required to obtain injunctive relief. And because it has failed to show a violation of a due process right, its Due Process and Declaratory Judgment claims must fail as well.

Irreparable Harm

There is no question Plaintiff may be potentially harmed by Defendant's inability to provide a timely hearing and decision by the ALJ, but the procedures in place do allow for rapid escalation up to a review by this Court after the time has run for a decision by the ALJ and the Board.

As discussed above, the Sixth Circuit has found that healthcare providers are not the

intended beneficiaries of the Medicare Act. "We begin by noting that participation in the Medicare program is a voluntary undertaking. *Baptist Hospital v. Secretary of Health & Human Services*, 802 F.2d 860, 869 (6th Cir.1986). Providers of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency. *See id.* at 869–870. Just as those who choose to serve individuals not covered by Medicare assume the risks of the private market, those who opt to participate in Medicare are not assured of revenues." *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720–21 (6th Cir. 1991).

Because this risk is well understood by healthcare providers prior to their participation as a Medicare healthcare provider, putting "all their eggs in one basket" represents a calculated risk a provider such as Plaintiff engages in when nearly eighty percent of its revenues are derived from Medicare. The Sixth Circuit in *Manakee Professional Medical Transfer Service, Inc. v. Shalala*, 71 F.3d 575 (1995) considered whether a healthcare provider in the Medicare program suffered irreparable harm if it was put out of business before it had exhausted its administrative appeals. The Sixth Circuit first noted that "monetary damages do not generally constitute irreparable harm." *Id* at 581. The Sixth Circuit next considered the above known risk a Medicare provider incurs when it decides to become a Medicare healthcare provider. In citing favorably the Eleventh Circuit case of *V.N.A. of Greater Tift County, Inc. v. Heckler*, 711 F.2d 1020, 1034 (11th Cir. 1983), the Sixth Circuit held "the companies' allegations of financial doom, even if they were substantiated, which they are not, would not necessarily warrant judicial waiver of the exhaustion requirement." In *Manakee*, the Sixth Circuit considered the *Tift* decision and

agreed with its conclusion that "even if the Secretary's actions were to force a healthcare provider out of the business, the injuries are not necessarily "irreparable" considering the risk known to the healthcare provider when it enters the Medicare program." *Manakee*, 71 F.3d at 581.

Here, Plaintiff has made the representation that its business relies heavily on Medicare revenues to the tune of almost 80% of its total revenue. If forced to pay the recoupment amount of over\$10,000,000.00 while also being denied payments until the recoupment amount is met, it will lose its business and the clients it serves will be forced to find other healthcare providers. While Plaintiff may not assert the rights of its patients to show irreparable harm, they also argue that they may lose these patients to competitors and this would have a severe impact on their continued viability. This supports Plaintiff's argument that it will be irreparably harmed should no injunction issue.

Defendants contend that Plaintiff's argument also serves to show that such an injunction would work against the public interest. If Plaintiff cannot repay the alleged overpayment incurred thus far, and should the Court enjoin recoupment with the Plaintiff still receiving alleged overpayments while the ALJ considers the issue, Plaintiff may incur even more overpayments that it would never be able to repay, depriving the public of additional limited funds.

The Court agrees that given the stronger likelihood that the overpayment decisions will be upheld on further review, the public interest in recoupment outweighs the risk of irreparable harm to Plaintiff.

Ultra Vires

Plaintiff's Ultra Vires claim seeks to enjoin Defendant from recouping overpayments

until an ALJ decision has been rendered in the allotted statutory time frame. According to

Plaintiff, this exceeds the authority of the Defendants under the Medicare Act. For the

reasons stated above, the Secretary is permitted to begin recoupment under the statute after

the second level of review and Plaintiff has the opportunity to escalate review under the

statute. Because Plaintiff has not demonstrated a due process violation, recoupment is

permitted at this stage of the proceedings and Plaintiff may escalate review in a relatively

brief period of time up to the district court level, Plaintiff's Ultra Vires claim fails as a matter

of law.

Therefore, for the foregoing reasons, Plaintiff's Motion for an Emergency Temporary

Restraining Order is denied and Defendants' Motion to Dismiss Plaintiff's claims is granted.

IT IS SO ORDERED.

s/ Christopher A. Boyko CHRISTOPHER A. BOYKO

United States District Judge

Dated: November 2, 2018

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